

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

Filed: October 6, 2020

|                     |   |                                      |
|---------------------|---|--------------------------------------|
| * * * * *           |   | UNPUBLISHED                          |
| KATHRYN CUMMINGS,   | * |                                      |
|                     | * | No. 18-195V                          |
| Petitioner,         | * |                                      |
| v.                  | * | Special Master Gowen                 |
|                     | * |                                      |
| SECRETARY OF HEALTH | * | Finding of Fact; Tetanus-Diphtheria- |
| AND HUMAN SERVICES, | * | acellular Pertussis (Tdap); Shoulder |
|                     | * | Injury Related to Vaccine            |
| Respondent.         | * | Administration (SIRVA); Site of      |
| * * * * *           | * | Administration; Onset.               |

*Michael P. Milmoie*, Law Offices of Leah V. Durant, LLC, for petitioner.

*Julia M. Collison*, United States Department of Justice, Washington, DC, for respondent.

### **FINDINGS OF FACT**<sup>1</sup>

On February 7, 2018, Kathryn Cummings (“petitioner”), filed a petition for compensation in the National Vaccine Injury Compensation Program.<sup>2</sup> Petitioner alleges that as a result of receiving a tetanus-diphtheria-acellular pertussis (Tdap) vaccination on May 18, 2017, she suffered a right shoulder injury related to vaccine administration (“SIRVA”) with onset of pain within forty-eight (48) hours, constituting an injury listed on the Vaccine Injury Table. Petition (ECF No. 1). For the reasons discussed below, I find that petitioner received the Tdap vaccination in her right arm and that the onset of petitioner’s right shoulder pain was within 48 hours thereafter.<sup>3</sup>

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<sup>1</sup> Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). “An objecting party must provide the court with a proposed redacted version of the decision.” *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes.** *Id.*

<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

<sup>3</sup> Pursuant to §300aa-13(a)(1), in order to reach my conclusion, I considered the entire record. This opinion discusses the elements of the record I found most relevant to the outcome.

## **I. Procedural History**

Petitioner's claim was originally assigned to the Chief Special Master's Special Processing Unit (SPU) docket. Notice of Assignment (ECF No. 4). Petitioner promptly filed her exhibits (Pet. Exs.) 1 – 6 and a Statement of Completion (ECF No. 10).

During the March 23, 2018 initial status conference, the OSM staff attorney managing the case in the SPU and the parties discussed the completeness of the record to date. Scheduling Order (ECF No. 11) at 1. Petitioner's counsel stated that Pet. Ex. 6 – Lotus Gynecology - represented petitioner's only medical records for the three years prior to vaccination. *Id.* He stated that petitioner was healthy prior to the vaccination. *Id.* Petitioner, herself a physical therapist, had been discharged from formal appointments and continued with a home exercise program. *Id.*

On December 12, 2018, respondent filed a status report advising that he had completed a preliminary review and requesting several categories of records. Resp. Status Report (ECF No. 21). On December 26, 2018, petitioner filed a status report stating that none of the requested records existed. Pet. Status Report (ECF No. 23). The following day, petitioner filed a supplemental Statement of Completion (ECF No. 25).

On April 2, 2019, respondent filed a status report advising that he was opposed to negotiating a potential settlement, intended to contest entitlement, and wished to file his Rule 4(c) report within sixty (60) days. Resp. Status Report (ECF No. 28).

On June 3, 2019, respondent filed the Rule 4(c) report, in which he recommended that compensation be denied. Resp. Report (ECF No. 29). As an initial matter, respondent noted that petitioner had submitted records of a gynecological visit listing prescriptions for numerous prescriptions but had provided no records explaining why they were prescribed. *Id.* at 2. Other records suggested potentially relevant medical care. *Id.* Accordingly, respondent argued that petitioner had not filed "sufficient medical records from before vaccination to allow for a determination whether petitioner's prior medical history could explain her shoulder symptoms." *Id.* at 6. Respondent also argued against compensation on the grounds that the record contained "conflicting evidence regarding the site of vaccination". *Id.* at 5. "Furthermore, by her own admission, petitioner did not experience symptoms with [sic? within?] forty-eight hours of vaccination, her symptoms were not limited to her shoulder, and a SLAP tear or shoulder atrophy, neither of which is related to vaccine administration, can explain her post-vaccination symptoms." *Id.*

On June 23, 2019, the Chief Special Master issued an order observing that the parties appeared to dispute whether additional medical records exist and further noted respondent's comments in the Rule 4(c) report about potential additional records. The Chief Special Master had reviewed petitioner's earlier status report on this point, filed December 26, 2018 (ECF No. 23). However, in order to resolve the parties' dispute, the Chief Special Master agreed with respondent's recommendations and ordered petitioner to file her insurance information, as well as the records from the pharmacy that filled petitioner's prescriptions, and ordered petitioner's counsel to subpoena all of her records from the urgent care center to ensure that the record was

complete. Scheduling Order (ECF No. 31). Petitioner duly filed her insurance records (Pet. Ex. 7), pharmacy records (Pet. Ex. 8), and subpoenaed urgent care records (Pet. Ex. 9), followed by a second supplemental Statement of Completion (ECF No. 41).

On December 11, 2019, the claim was randomly reassigned to my docket. Notice of Reassignment (ECF No. 43). During my initial status conference on February 20, 2020, ???counsel advised that respondent made another request for records from providers identified in the pharmacy records, at Pet. Ex. 8. Petitioner had agreed to obtain and file those records. I directed petitioner and her counsel to carefully review her medical history and obtain and file all medical records required by Section 11(c) of the Vaccine Act and/or requested by respondent. Scheduling Order (ECF No. 44).

On March 13, 2020, petitioner filed records from Texas Orthopedics (Pet. Ex. 10), Seton Spine and Rehab Center (Pet. Ex. 11), and Rediclinic Round Rock (Pet. Ex. 12), followed by her third supplemental Statement of Completion (ECF No. 46). On April 15, 2020, respondent filed a status report advising that he did not believe that the records were complete. Specifically, respondent requested “complete medical records pertaining to petitioner’s right elbow fracture suffered approximately two months prior to vaccination”. Resp. Status Report (ECF No. 47). Respondent cited to the record from petitioner’s one consult at Texas Orthopedics on March 12, 2019, which provides: “She does have a history of trauma to the elbow two years ago. She had what sounds like a medial collateral ligament avulsion fracture. This was managed non-operatively and she has had no issues with the elbow until recently.” Pet. Ex. 10 at 17. On April 19, 2020, petitioner filed a status report advising that this notation in fact described two separate events: (1) approximately two years prior to the appointment, she suffered a shoulder injury which made it difficult to sleep on her right side or lift anything normally, which put pressure on her right side; and (2) an injury to her right elbow sustained during a minor skiing accident in 2004. Pet. Status Report (ECF No. 48). Petitioner concurrently filed her fourth supplemental statement of completion (ECF No. 49). I ordered respondent to file another status report indicating whether the record was sufficiently complete. Scheduling Order (ECF No. 50). On May 6, 2020, respondent filed a status report stating that to the extent that the records requested in his prior status report (ECF No. 47) did not exist, he had no further request that petitioner file additional records at this time. Resp. Status Report (ECF No. 51).

On July 29, 2020, I convened another status conference to set further proceedings. Both parties requested resolution of disputed facts, namely (1) the site of vaccine administration and (2) onset of petitioner’s injury. I agreed to hold a fact hearing. Respondent’s counsel noted that petitioner made certain representations in a status report (ECF No. 48) which would be better suited for an affidavit. I added that petitioner should consider providing additional detail about her recollections about the site of vaccine administration and onset of her injury. Petitioner should also have any other individual(s) with independent recollections of those issues submit their own affidavits and testify at the fact hearing. While I agreed to hold a fact hearing for purposes of resolving only the site of vaccine administration and onset, I stated that the parties may take the opportunity to also obtain testimony regarding petitioner’s pain and suffering and residual symptoms. Scheduling Order (ECF No. 55).

On July 30, 2020, petitioner filed her supplemental affidavit (Pet. Ex. 13) as well as affidavits from her daughter (Pet. Ex. 14), son (Pet. Ex. 15), and husband (Pet. Ex. 15).

On August 21, 2020, a fact hearing took place over videoconference with all participants appearing remotely. The witnesses were petitioner, her daughter, her son, and her husband. At the conclusion of the fact hearing, I asked whether there was any other evidence that needed to be presented before I decided the disputed issues. Both parties said no. The parties did not request briefing. Accordingly, I provided a brief bench ruling that petitioner had established preponderant evidence that she had received the Tdap vaccination in her right arm and that the onset of her right shoulder pain was within 48 hours thereafter. Written findings of fact would be issued following receipt of the transcript. *See* Scheduling Order filed August 25, 2020 (ECF No. 60); Transcript filed September 9, 2020 (ECF No. 62). This matter is now ripe for adjudication.

## **II. Legal Standard**

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at \*19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” § 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

### **III. Findings of Fact**

#### **1. Site of Vaccination**

The first factual issue to be resolved is whether the May 18, 2017 Tdap vaccine was administered into petitioner’s right arm, as alleged as part of her right shoulder injury claim. 42 C.F.R. §§ 100.3(a), (c)(10). I have completed a review of the record to include all medical records, affidavits, testimony, expert reports, respondent’s Rule 4(c) report, and additional evidence filed. I found the following evidence to be most relevant to resolution of this issue:

- The record of petitioner’s encounter at MedSpring Urgent Care on May 18, 2017, signed at 10:05 PM by Heather Cain, PA, which provides: “Immunization: Tdap Vaccine, >7 years, IM: .5 mL given by Sarah Powers, SP on Left Deltoid.” Pet. Ex. 9 at 12.
- The tetanus vaccine consent form also from May 18, 2017, which reflects one individual’s handwriting including the misspelling of petitioner’s first name as “Kathrine” and petitioner’s own handwriting and signature reflecting the correct spelling of her first name as “Kathryn”. On the bottom of the form “for office use”, is affixed the vaccine administration sticker providing the brand name, batch and lot numbers, and expiration date. Directly to the left, under site of administration, “right deltoid” is checked. Pet. Ex. 1 at 1. I find – particularly based on the vaccine administration sticker – that this record is more contemporaneous and more likely to be accurate than the urgent care encounter record, with respect to the site of vaccine administration.

- Petitioner’s testimony that she received the May 18, 2017 Tdap vaccination in her right arm. Pet. Ex. 5 at ¶¶ 1-2; Pet. Ex. 13 at ¶¶ 1-3; Tr. 31, 36.
- Petitioner’s testimony that she is right-handed. *See* Pet. Ex. 4 at 14, 17; Tr. 31.
- Petitioner’s testimony that she has been working as a physical therapist for several decades and that years ago, another physical therapist had said “if you relax your arm while you get [injections] and you don’t tense up, that it doesn’t hurt as much in the long run”. Tr. 32. Petitioner testified: “I can relax my right arm more controllably than my left. So I just always have gotten my shots in the right arm because of that.” *Id.* She recalled requesting the Tdap vaccination in her right arm for that reason. Tr. 56-57; *see also* Pet. Ex. 16 at ¶ 2, Tr. 110 (husband’s recollection).
- Petitioner’s testimony, which I found to be credible that she attempted to amend the urgent care records for several reasons. These included her desire to have accurate medical records that would guide appropriate treatment decisions going forward. She also wanted to hold the urgent care facility accountable for her injury. In addition, she wanted documentation to support her vaccine injury claim for which she first contacted counsel in June 2017. Pet. Ex. 9 at 12, 13, 15; discussed at Tr. 18, 21-22, 33-35, 65-68.

Based on the above, I find that there is preponderant evidence that the May 18, 2017 Tdap vaccine was administered in petitioner’s right arm.

## **2. Onset of Right Shoulder Pain**

The second factual issue is whether petitioner’s first symptom or manifestation of onset of right shoulder pain was within 48 hours after administration of the May 18, 2017 Tdap vaccine. 42 C.F.R. §§ 100.3(a), (c)(10). Again, I have completed a review of the record to include all medical records, affidavits, testimony, expert reports, respondent’s Rule 4(c) report, and additional evidence filed. I found the following evidence to be most relevant to resolution of this issue:

- The May 18, 2017 urgent care encounter record, which is signed at 10:05 PM by Heather Cain, PA. Pet. Ex. 9 at 12.
- The record reflecting that the urgent care facility submitted the reimbursement claim to petitioner’s health insurer the following day. Pet. Ex. 9 at 9.
- The May 27, 2017 urgent care telephone encounter record which provides: “[S]he was fine in the initial days following the injection, but 5-6 days later she developed a deep dull ache... her pain has been present for 3 days at this point.” Pet. Ex. 9 at 15.
- The June 2, 2017 urgent care encounter record which provides: “44 y/o female presents to the US today with c/o R arm and shoulder pain onset x1.5 weeks. She reports she was seen about 2 weeks ago in clinic after she had stepped on a board with rusty nails. She was given a tetanus vaccine. She didn’t have any pain for the first few days but by the 3<sup>rd</sup>

or 4<sup>th</sup> day she began to have R upper arm pain radiating from the R side of her neck into her R shoulder. After she did some research, she found it could be related to the tetanus vaccine...” Pet. Ex. 9 at 18.

- *But see* addendum reflecting that in January 2018, petitioner called to say that the urgent care records were not correct, specifically because “the shot was given so late on Thursday evening”, onset was indeed within 48 hours. Pet. Ex. 9 at 12-13.
- The July 12, 2017 orthopedics consult record which provides petitioner’s history that after she received the Tdap vaccination, “[s]he developed pain in the right shoulder at 48 hours.” Pet. Ex. 3 at 2.
- The August 7, 2017 physical therapy new patient questionnaire, on which petitioner wrote that the onset of her right shoulder injury was on May 18, 2017. Pet. Ex. 4 at 33.
- The testimony that petitioner presented to MedSpring Urgent Care on May 18, 2017 at approximately 9:00 p.m., when it was about to close, after attending a banquet recognizing Special Olympics athletes and volunteers (including her daughter) earlier that evening. Pet. Ex. 5 at ¶ 1 and Tr. 7-9; *see also* Pet. Ex. 14 at ¶ 2 and Tr. 98-99 (daughter’s recollection); Pet. Ex. 16 at ¶ 2 and Tr. 110 (husband’s recollection).
- Petitioner’s testimony that after she received the Tdap vaccination in her right arm, it was sore and she had to use her left arm to steer while driving home. Tr. 31.
- The testimony that petitioner’s right arm was heavier and achier than it usually was after other injections, such as flu vaccinations, that evening. Pet. Ex. 13 at ¶ 3 and Tr. 9, 33 (petitioner); *see also* Pet. Ex. 14 at ¶ 2 and Tr. 98-99 (daughter); Pet. Ex. 16 at ¶ 2 and Tr. 110 (husband).
- The testimony that petitioner had previously planned to assist children with special needs at a field day on Friday, May 19, 2017. That day due to petitioner’s right arm pain, she began taking Advil; her husband loaded supplies into the car; and her daughter accompanied her to assist at the field day including to pull a child in a wagon. Tr. 12-13, 31, 33; *see also* Pet. Ex. 14 at ¶ 2 and Tr. 99-100 (daughter); Pet. Ex. 16 at ¶ 2, Tr. 110-11 (husband).
- The testimony that on Saturday, May 20, 2017, petitioner’s right shoulder pain was worse and she couldn’t even lift her arm up overhead to paint a patio cover. Pet. Ex. 13 at ¶ 2 and Tr. 13; *see also* Pet. Ex. 15 at ¶ 2 and Tr. 88-89 (son).
- The testimony that petitioner and her husband had previously planned to go out the evening of May 20, 2017, for dinner and a movie to celebrate their anniversary which was the following day. Due to petitioner’s right shoulder pain, the daughter helped do her hair. Petitioner and her husband went to dinner but skipped the movie because of her shoulder pain. They got home before 9:00 p.m. Upon returning home, petitioner took more Advil, went to bed early, but couldn’t bear to sleep on her right side as she was

accustomed, because of pain “digging” into her shoulder. Pet. Ex. 13 at ¶ 2 and Tr. 13-14, 35 (petitioner); Pet. Ex. 14 at ¶ 2 and Tr. 100-01 (daughter); Pet. Ex. 16 at ¶ 3, Tr. 111-13 (husband).

- Petitioner’s summary of the 48 hours after her Tdap vaccination: “Initially, Thursday [May 18, 2017] evening, Friday [May 19, 2017], during those times, I was attributing it to just the normal ache and pain that you get from getting a shot... And then on Saturday [May 20, 2017] when that deep, deep pain began, that’s when I started getting really, really worried that it wasn’t just going to be soreness right now, that something was not right.” Tr. 37; *see also* Pet. Ex. 5 at ¶ 1; Pet. Ex. 13 at ¶¶ 3-4.

I find that there is preponderant evidence that petitioner received the Tdap vaccination on May 18, 2017 in the late evening at approximately 9:00 p.m. While the most contemporaneous records, from the urgent care facility, state that petitioner did not experience the onset of right shoulder pain within 48 hours, those records also reflect petitioner’s request to correct the records just a few months later. As noted above, I find credible that she had several good faith motivations for seeking to amend the records. *See* Tr. 18, 21-22, 33-35, 65-68. The less contemporaneous orthopedics and physical therapy records are also presumed to be accurate and those support onset within 48 hours. I also find “consistent, clear, cogent, and compelling” the testimony from petitioner and her family members that onset of her right shoulder pain was within 48 hours of the Tdap vaccination, as related to specific life events (particularly the Special Olympics banquet before vaccination as well as the field day and planned anniversary celebration within 48 hours post-vaccination).

Accordingly, I find that there is preponderant evidence that petitioner experienced the onset of right shoulder pain within 48 hours, indeed immediately, after the May 18, 2017 Tdap vaccine administration.

#### **IV. Conclusion and Further Proceedings**

As requested by the parties, I have made formal findings of fact that (1) there is preponderant evidence that the May 18, 2017 Tdap vaccine was administered in petitioner’s right arm and (2) there is preponderant evidence that petitioner experienced the onset of right shoulder pain within 48 hours, indeed immediately, after the May 18, 2017 Tdap vaccine administration.

While this is not disputed between the parties, I would be prepared to find that there is also preponderant evidence that petitioner’s right shoulder injury has persisted for more than six months.

While respondent, in his earlier status reports and Rule 4(c) report, asked whether there were additional medical records from the three years prior to the vaccination and afterwards, petitioner has addressed those requests. Respondent, in his latest status report on this issue (ECF No. 51), stated that he had no further request for his additional records. Additionally, during the fact hearing, respondent’s counsel questioned thoroughly about whether any additional records existed; the witnesses answered that there were none and I found their answers to be credible.

Consistent with my prior scheduling order on August 25, 2020 (ECF No. 60), petitioner has conveyed a demand to respondent. *See* Pet. Status Report filed September 23, 2020 (ECF No. 63).

It is hereby **ORDERED** that respondent shall file a status report proposing further proceedings **within 30 days, by Thursday, November 5, 2020.**

**IT IS SO ORDERED.**

**s/Thomas L. Gowen**  
Thomas L. Gowen  
Special Master